OCT 18 2011

510(k) Summary

per 21 CFR §807.92 (c)

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
Contact Name and Information	Shannon Pettit Senior Regulatory Affairs Specialist Tel: 763-494-2833 Fax: 763-494-2222 E-mail: Shannon.Pettit@bsci.com		
Date Prepared	20 September 2011		
Trade Name	V-14™ ControlWire® Guidewire		
Common Name	Wire, Guide, Catheter		
Classification	Class II		
Product Code	DQX (21 CFR 870.1330)		
Predicate Device	Boston Scientific PT Graphix Guidewire (Formerly SCIMED ChoICE PT Vision)	K962572	SE: 17 Dec 1996
Reason for Submission	To gain clearance for the V-14 ControlWire Guidewire based on a narrowed intended use of the currently marketed PT Graphix Guidewire cleared under K962572.		
Device Description	The V-14 ControlWire Guidewire is a hydrophilic coated polymer tipped guide wire intended to facilitate the placement of balloon dilatation catheters, and/or other therapeutic devices during peripheral vascular procedures. V-14 ControlWire core wire is constructed using 304V stainless steel wire. The distal portion of the core wire is tapered in diameter to provide added flexibility. The distal portion of the core wire is covered by a two part polymer sleeve. The polymer sleeve is coated with a hydrophilic coating to create a lubricious surface and improve wire handling. The proximal portion of the core wire is coated with polytretraflouroethylene (PTFE). The V-14 ControlWire comes in two length configurations (182 cm and 300 cm), two distal tip configurations (Straight and Angled) and two taper lengths (Short Taper and Long Taper).		

Indications for Use	The V-14 ControlWire Guidewires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures. The V-14 ControlWire Guidewires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.
Comparison of Technological Characteristics	The narrowed intended use of the V-14 ControlWire Guidewire as compared to PT Graphix Guidewire does not affect or alter the fundamental scientific technology of the cleared components. The design, operating principles, shelf-life, materials, construction, accessories, performance, sterilization method, and manufacturing of the devices will remain unchanged.

Non-Clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical performance data submitted in support of the overall safety and efficacy of the device is based on the Failure Modes/Effects Analysis (FMEA) risk analysis method completed for the V-14 ControlWire to demonstrate that the proposed devices are suitable for their intended use. All testing performed and data demonstrate passing results according to executed verification protocols. Therefore, results of non-clinical performance data, including biocompatibility, sterility, and packaging testing, supports the safety and efficacy of the V-14 ControlWire Guidewires. The following performance tests were performed: ♦ Torqueability ♦ Radiopacity ♦ Polymer sleeve lubricity / wire movement ♦ Magnetic segment resiliency ♦ Magnetic performance ♦ Distal tip tensile ♦ Proximal tensile ♦ Surface Inspection ♦ Bends ♦ Corrosion resistance ♦ Flexing test ♦ Biocompatibility: o Cytotoxicity o Sensitization o Intracutaneous Reactivity o Acute Systemic Toxicity o Materials Mediated Rabbit Pyrogen o Hemolysis Direct o Partial Thromboplastin Time o In Vitro Hemocompatibility Assay o Complement Activation o USP Physicochemical o Latex ♦ Tip flexibility ♦ Coating adherence ♦ Coating durability – distal ♦ Magnetic section kink resistance ♦ Magnetic section joint kink resistance / fatigue ♦ J-tip / angled tip retention ♦ Torque strength ♦ Polymer sleeve shear ♦ Overall length ♦ Fracture test
Clinical Performance Data	Clinical Evaluation was not required for these devices.
Conclusion	Based on the Indications for Use, unaltered technological characteristics, and submitted non-clinical performance data, the Boston Scientific V-14 ControlWire Guidewire is shown to be appropriate for its intended use and is considered to be substantially equivalent to the PT Graphix Guidewire (K962572).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
% Ms. Shannon Pettit
One Scimed Place
Maple Grove, MN 55311-1566

OCT 1 8 2011

Re: K112745
Trade/Device Name: V-14 ControlWire Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 20, 2011
Received: September 21, 2011

Dear Ms. Pettit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112745

Device Name: V-14™ ControlWire® Guidewire

Indications for Use:

The V-14 ControlWire Guidewires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures.

The V-14 ControlWire Guidewires are not intended for use in the cerebral vasculature.

The devices are provided non-pyrogenic, sterile, and intended for one procedure only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112745